

Understanding expectancies in cancer symptom management (Ro1)

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Cancer Symptom Management: Unmet Needs

The number of cancer survivors is increasing, but advances are accompanied by increasing symptom burden

Despite evidence-based protocols, many patients have unmet pain and symptom management needs

Disparities in symptom management affect medically underserved patients/ survivors

Harnessing expectancies may help to address unmet needs in symptom management

Expectancies: beliefs about one's future outcomes, evoked by social, psychological, environmental, and systemic factors

Expectancy effects: non-volitional, cognitive, behavioral, and biological outcomes caused by expectancies

Expectancies

Examples of expectancies include:

- Beliefs about treatment efficacy
- Prognostic beliefs
- Perceived likelihood of symptoms and side effects of cancer and cancer treatments

Can be informed by, but are distinct from:

- Self-efficacy for managing symptoms
- Medical trust/ mistrust
- Feelings about cancer treatment and symptoms

Expectancy Effects

- Are routinely leveraged in cancer care, but often in an intuitive manner
 - Onfidence, empathy, encouragement, optimism
 - Vagueness about the chance of treatment success
 - "Hope for the best but expect the worst"
- Can also result from expectancies of clinicians, caregivers



Expectancy in Active Treatment

- We do not know the magnitude of treatment cancer symptom treatment efficacy due to expectancy vs. active treatment
 - Patients report less pain when they believe they are receiving treatment (but before it begins)
 - Morphine more effective when paired with information about its pain-relieving properties (vs. no information)
 - Propranolol better than placebo for treating chronic pain, but only among those with modest treatment expectancies

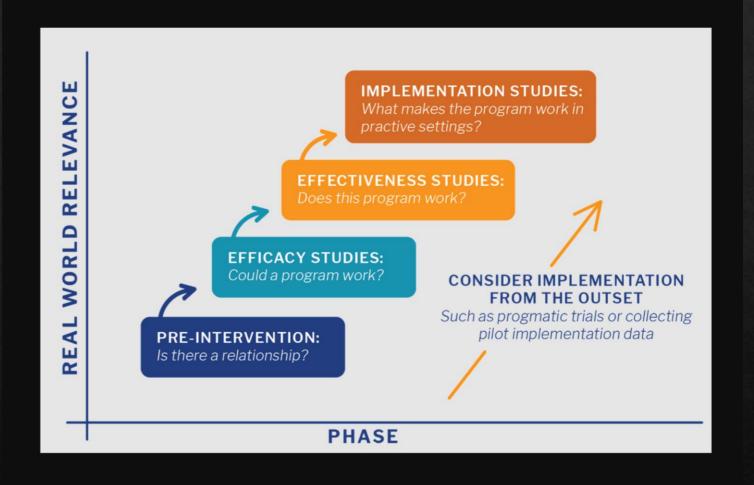


Disparities in Expectancy Effects

- Expectancy effects:
 - Are unevenly distributed and may contribute to cancer disparities
 - Can result from differences in physician warmth, empathy, support
- Scant research on expectancy effects among medically underserved groups



The purpose of this PAR is to support the systemic study of expectancygenerating factors and measure their effects on expectancies and symptom management



Experimental Medicine Approach



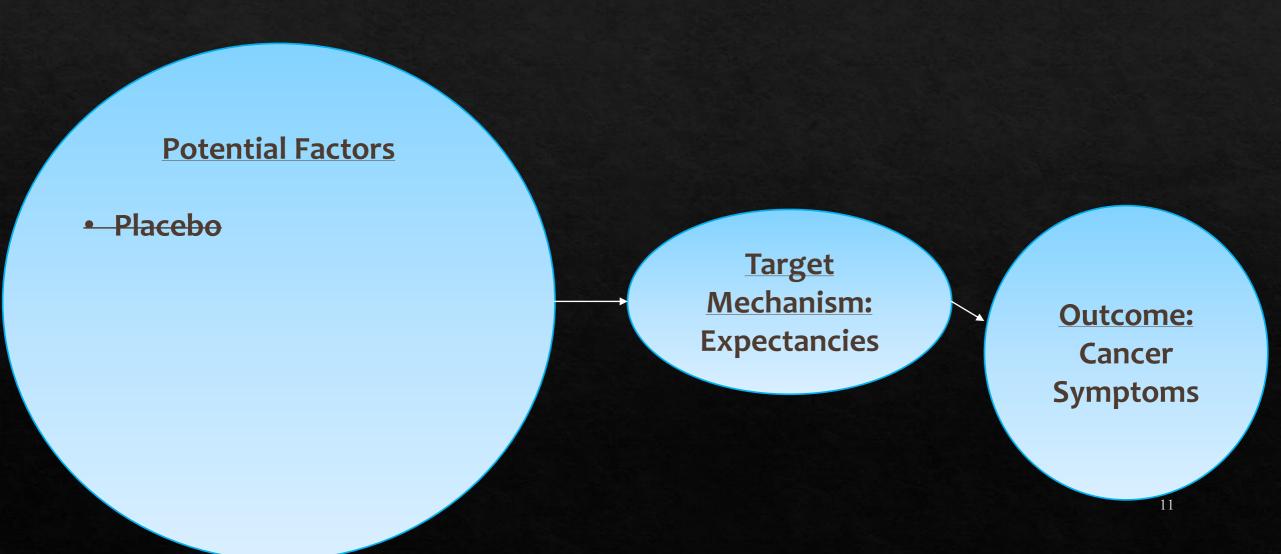
- Operates within definition of NIH Clinical Trials
- Identify malleable target expectancies that should affect cancer symptom outcomes
- Identify appropriate and validated measures to reliably capture change in target expectancies and outcomes
- Plan analyses to demonstrate that:
 - ♦ Target expectancies can be experimentally manipulated with one or more factors
 - ⋄ Target expectancies are associated with outcomes
 - Changes in target expectancies are causally related to changes in outcomes

Potential Factors

Placebo

Target
Mechanism:
Expectancies

Outcome:
Cancer
Symptoms



Potential Factors

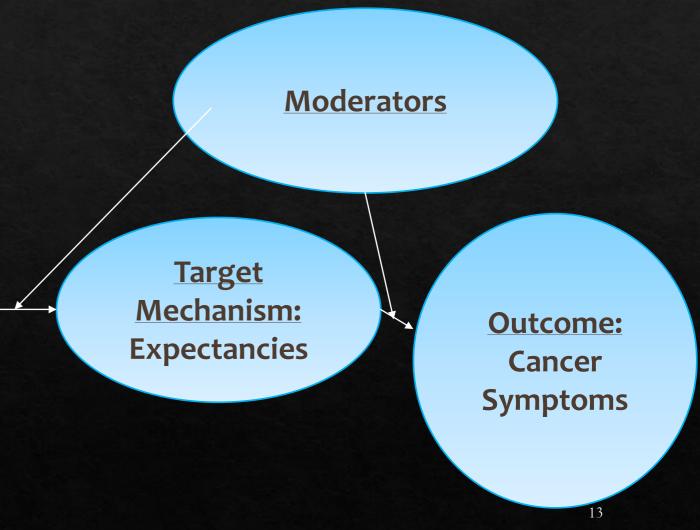
- Placebo
- Clinical environment
- Treatment characteristics
- Clinical interaction
- Information

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Concept

- Program Announcement with Special Receipt and Review (Ro1)
- ♦ Grants awarded within yearly NCI payline (no set-asides)
- Projects to develop and test expectancy-generating factors in clinical cancer care settings
 - Identify a clinical use case, patient population, factors(s) and target(s)
 - ♦ Test this combination using experimental medicine approach
- Fund focused awards over multiple years to facilitate investigator network



Example Research Topics

What multilevel factors contribute to expectancy effects in cancer symptom management and how can we effectively manipulate them?

What variables moderate expectancy effects in cancer symptom management, and can we identify a phenotype for expectancy susceptibility?

What factors
contribute to
disparities in
expectancy effects in
cancer symptom
management?

Responsiveness/ Special Review Criteria

- Conducted in clinical setting
- Includes MD or equivalent expertise
- Consideration of specific patient population (e.g., heterogeneity of patient population/ symptoms, consideration of groups most at risk for unmanaged symptoms)
- ♦ No deception/ placebo

BSA Member Feedback

- Broad focus on symptoms (not prioritizing pain)
- Explicit discussion of deliverables within the experimental medicine context/ role of mechanistic research in translational continuum
- ♦ Clarification of:
 - ♦ Inclusion of provider/ family expectancies
 - Examples of potential factors that can engage targets
 - Meaning of non-deceptive study conditions
 - ♦ Instructions to carefully consider participants